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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/358,141	07/20/1999	JEFFREY R. SAMPSON	10990393-1	1170

22878 7590 12/17/2003

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EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/358,141	SAMPSON, JEFFREY R.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-24* is/are pending in the application.

4a) Of the above claim(s) *10-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office action is in response to the communications filed 9-24-03.

Claims 1-8, 10-24 are pending in the instant application. Claims 10-18 have been withdrawn as being drawn to non-elected inventions. Claims 1-8 and 19-24 have been examined on their merits as indicated in the Office action below. The amendments filed 8-24-03 appears to be missing a portion of claim 19 (see pages 3-4 of this communication). The version of claim 19 that has been examined in this Office action relies upon the version of claim 19 filed July 1, 2003.

Response to Arguments and Amendments

Maintained Rejections

Claims 1-8 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 1-2-03.

Applicant's arguments filed 9-24-03 have been fully considered but they are not persuasive. Applicants argue that the rejection is improper and that the instant disclosure has adequate written description because the examiner mistakenly required that every conceivable embodiment fall within the claims must be performed successfully and that by using such stringency, no generic claims would be allowable where the examiner can imagine or point to a single inoperative embodiment. Contrary to Applicants' assertions, the genera listed in the claims, including "unstructured nucleic acid(s)," which nucleic acids are "substantially complementary" to a first template

sequence element, as well as "purine analog(s)" and "pyrimidine analog(s)" encompass very large number of species and the instant disclosure does place any limit on the structural variants encompassed within each of these broad genera. Concise structural features that could distinguish compounds in the genus from others are missing from the disclosure and claims. The disclosure fails to describe the common attributes or characteristics concisely identifying members of the genera comprising unstructured nucleic acids that are substantially complementary to a first template, purine analogs or pyrimidine analogs. And because each genus is highly variant, the description provided is insufficient. The specification teaches the use of various purine and pyrimidine analogs (e.g. as listed in claims 3-8 and 19-24) in synthesizing nucleic acids that incorporate these modified nucleobases, thereby imparting reduced intramolecular and increased intermolecular base pairing via hydrogen bonding between complementary strands. The specification also teaches (e.g. on pages 27-29 of the specification) an alteration in secondary structure of double stranded nucleic acids upon incorporation of some of the specifically listed purine and pyrimidine analogs. The examples of the purine and pyrimidine analogs provided in the instant specification, however, are not sufficiently representative of the incorporation of the broad genera comprising all purine and pyrimidine analogs. And the known changes in secondary structure of the double stranded nucleic acids following incorporation of the analogs listed in claims 3-8 and 19-24 do not represent "unstructured" nucleic acids. Therefore, the instant rejection for lacking adequate written description for the broad genera claimed is hereby maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 19-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 09/632,639. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of synthesizing nucleic acids with reduced intramolecular base pairing and increased intermolecular base pairing upon incorporation of nucleotide analogs including 2-aminodeoxyadenosine 5'-triphosphate, 2-thiodeoxythymidine (or –cytidine) 5'-triphosphate, deoxypyrrolopyrimidine 5'-triphosphate, and deoxyinosine 5'-triphosphate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Vivekananda et al.

Vivekananda et al teach methods comprising synthesizing nucleic acid molecules with a reduction or alteration in secondary structure (see especially col. 2, lines 20-65; col. 3, line 44-col. 5, line 67; col. 6, line 62-col. 10, line 31), comprising the polymerization of nucleotide precursors from a DNA or RNA template by an appropriate polymerase or transcriptase (see especially col. 22, line 29-col. 24, line 45), and which nucleotide precursors include 2-aminodeoxyadenosine 5'-triphosphate, 2-thiodeoxythymidine 5'-triphosphate, and inosine triphosphate (see especially col. 20, line 14-col. 22, line 9), whereby a nucleic acid molecule with reduced levels of cross-hybridization is synthesized.

Claims 1-8 and 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kutyavin et al.

Kutyavin et al teach methods of synthesizing nucleic acid molecules with reduced or secondary structure (see the abstract; col. 2, line 33- col. 9, line 53; claims 1-20, 23-25), comprising the polymerization of nucleotide precursors from a DNA or RNA template by an appropriate polymerase or transcriptase, (see col. 18 and 22-23), and which nucleotide precursors include 2-aminodeoxyadenosine 5'-triphosphate, 2-thiodeoxythymidine or -cytidine, 5'-triphosphate, pyrrolo-pyrimidine triphosphate, inosine triphosphate (see col. 5, col. 34, lines 53- 67), whereby a nucleic acid molecule with reduced levels of cross-hybridization is synthesized (see abstract; text in col. 4; claims 1-20) .

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ

12/9/03